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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/077,893 02/19/2002 Thomas H. Foster BTI-13 3097 37211 7590 03/09/2004 **EXAMINER BASCH & NICKERSON LLP** GETZOW, SCOTT M 1777 PENFIELD ROAD PENFIELD, NY 14526 ART UNIT PAPER NUMBER 3762 DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application	No.	pplicant(s)	7
		10/077,893		FOSTER ET AL.	
	Office Action Summary	Examiner		Art Unit	
		Scott M. Get		3762	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)	Responsive to communication(s) filed on				
2a) <u></u> ☐	This action is FINAL . 2b)⊠ This action is non-final.				
3) 🗌	, , , , , , , , , , , , , , , , , , , ,				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>1-43</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5)⊠	5)⊠ Claim(s) <u>38,39,42 and 43</u> is/are allowed.				
6)⊠	6)⊠ Claim(s) <u>1-37,40 and 41</u> is/are rejected.				
7)	7) Claim(s) is/are objected to.				
8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
9) The specification is objected to by the Examiner.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:					
1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority document	ts have been	eceived in Application	on No	
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date					
	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5	Notice of Informal Pa		52)
	r No(s)/Mail Date <u>9,11</u> .		Other:		

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Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1,2,7,16,19,37,40,41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier '142 in view of Nappholz et al '227.

Mulier teaches all of the subject matter of the above claims except the explicit mention of a detection circuit to detect a phase timing of an external electromagnetic field. Nappholz teaches EMI detection in a pacemaker. In column 5, lines 15-22 of Nappholz, it is taught that timing between feature of a external EMI can be used to alter the functioning of the implanted device to avoid interference. It would have been obvious to have such a detection circuit in the device of Mulier in order to further prevent externally produced EMI from interfering with the operation of the pacemaker. Further, it is implicit in Mulier that a control circuit is contained inside container 11 since it would not work otherwise. Also, to have a microprocessor as the control circuit is also obvious in that modern day pacemakers all have sophisticated processors that handle signal detection and analysis. Still further, since the device of Mulier is implanted in the body, it must have a biocompatible outer cover otherwise adverse tissue reaction would occur which would necessitate the removal of the device from the body.

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3. Claims 3,4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier and Nappholz and further in view of Luo et al (article titled 'Electromagnetic interference shielding using continuous carbon-fiber carbon matrix and polymer-matrix composites').

Luo teaches using carbon as well as polymer as shielding to prevent interference from external electromagnetic fields. It would have been obvious to use such in place of the metallic shield of Mulier since such shielding has been shown to be effective in attenuating EMI.

- 4. Claims 5,6,17,18,27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier and Nappholz and further in view of Lindegren et al '837.
 - Mulier and Nappholz teach all of the subject matter of the above claims except a fiber optic communication system. Lindegren teaches such a system including optical conductors 10,22 used with an implanted pacemaker. The optical conductors allow for energy and data transfer without noise interference. Thus, it would have been obvious to use such optical conductors and associated circuitry of Lindegren in order to avoid EMI and thus provide for greater patient safety.
- 5. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier and Nappholz and further in view of Kobayashi et al '095.

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A second shielding made from metal, carbon or polymer, as shown by

Kobayashi, would have been obvious to use with the combination of Mulier and

Nappholz since such has been shown to provide good protection from

electromagnetic interference for implanted leads, thus further increasing the

safety of the patient during exposure to EMI.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier and Nappholz and further in view of Tsitlik et al '010.

Tsitlik teaches the use of electrical filters for each lead of an implanted device, used during MRI. To have lead filters, as shown by Tsitlik, with the device of Mulier and Nappholz would have been obvious since such would provide extra protection for the patient from interference that would not be detected by the detection circuitry of Nappholz.

- 7. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier, Nappholz, Tsitlik, and further in view of Kobayashi et al '095.
 - It would have been obvious to use the shielding taught by Kobayashi with the device of Mulier, Nappholz and Tsitlik for reasons mentioned supra.
- 8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier, Nappholz and further in view of Juran et al '675.

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Juran teaches an implanted device with the capability to monitor battery power and give an indication for elective replacement. Such capability is useful in the art to provide the patient with advance warning of battery depletion so that arrangements can be made, and thus would have been obvious to use with the device of Mulier and Nappholz.

9. Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier, Nappholz and further in view of McClure et al '734.

McClure teaches the use of digital filters, see column 7 lines 30-49. Such filters are common in the art to help in the detection process of physiological signals and have been shown to be effective in so doing. Therefore, it would have been obvious to use digital filtering, as shown by McClure, with the device of Mulier and Nappholz.

Allowable Subject Matter

10. Claims 38,39,42,43 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott M. Getzow whose telephone number is (703) 308-2997. The examiner can normally be reached on M-F, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott M. Getzow Primary Examiner Art Unit 3762

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